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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Anja EITRICH et al.

Confirmation No. 5886
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Examiner: Browe, David

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For : COSMETIC AND DERMATOLOGICAL SELF-TANNING FORMULATIONS COMPRISING DIHYDROXYACETONE AND GLYCERIN

REPLY BRIEF UNDER 37 C.F.R. § 41.41(a)(1)

Commissioner for Patents
U.S. Patent and Trademark Office
Customer Service Window, Mail Stop Appeal Brief - Patents
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir:

This Reply Brief is in response to the Examiner's Answer mailed February 15, 2011, the period for reply extending until April 15, 2011.

In the Examiner's Answer all grounds of rejection set forth in the final rejection are maintained.

Appellants note that the Examiner's Answer does not sufficiently address several of Appellants' arguments as to why the rejections are without merit, and misrepresents some of the facts. These deficiencies have prompted the present Reply Brief.

Appellants also note that this Reply Brief is being filed under 37 C.F.R. § 41.41(a)(1) and is directed to the arguments presented in the Examiner's Answer, and therefore must be entered unless the final rejection is withdrawn in response to the instant Reply Brief.

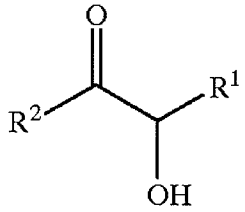
In order to avoid repetition, the following response to the Examiner's arguments in the Examiner's Answer is limited to issues which are important enough to warrant a further

comment in Appellants' opinion. Accordingly, Appellants' silence with respect to any allegations set forth in the Examiner's Answer that are not specifically addressed below should by no means be construed as Appellants' admission that these allegations are of any merit.

REPLY

Appellants point out again that the disclosure of STROUD (U.S. Patent No. 6,231,837) is extremely broad. In particular, the compositions of STROUD may comprise, *inter alia*, from about 0.5 % to about 20.0 % by weight of any self-tanning skin coloring agent subject to chemical instability and from about 0.1 % to about 15.0 % by weight of any polyol comprising a polyhydric compound having at least three hydroxyl groups and at least three carbon atoms.

Further, even if one takes into account the somewhat more specific disclosure of STROUD, the compositions disclosed therein may contain, as self-tanning skin coloring agent subject to chemical instability, any of the 14 α-hydroxy aldehydes or ketones of formula:



wherein R^1 is H, CH_2OH, $CHOHCH_2OH$, $CH(OH)CH(=O)$, $CH(OCH_3)CH(=O)$, $CH(NH_2)CH(=O)$, or CH(NH-Phenyl)CH(=O); and R^2 is H or CH_2OH. See col. 9, lines 28-44 of STROUD.

In other words, preferred self-tanning skin coloring agents subject to chemical instability according to STROUD can be as different as, for example,

hydroxyacetaldehyde (R^1 = R^2 = H; molecular weight about 80) and 4-oxo-2-phenylamino-3,5-dihydroxy-pentanal (R^1 = CH(NH-Phenyl)CH(=O) and R^2 = CH_2OH; molecular weight about 210).

Similarly, a preferred polyol comprising a polyhydric compound having at least three hydroxyl groups and at least three carbon atoms according to STROUD can be any of the following 18 compounds or groups of compounds: 1,2,6-hexanetriol, isopropylidene glycerol, polyoxyethylene sorbitols, glycerin (glycerol), diglycerin, erythritol, mannitol, xylitol, D and L-sorbitol, glucose, fructose, galactose, mannose, sucrose, lactose, trehalose, maltose and inositol. See, e.g., col. 7, lines 35-43 of STROUD.

In other words, the preferred polyols of STROUD can be as different as, for example, glycerin (3 hydroxy groups, 3 carbon atoms, molecular weight about 92) and inositol (6 hydroxy groups, 6 carbon atoms, molecular weight about 180) or a polyoxyethylene sorbitol such as, e.g., trioxyethylene sorbitol (6 hydroxy groups, 12 carbon atoms, molecular weight about 314).

In view of the large variety of both the (preferred) self-tanning skin coloring agents subject to chemical instability and the (preferred) polyols which can be employed according to STROUD, one of ordinary skill in the art will readily recognize that not each and every self-tanning skin coloring agent subject to chemical instability can be employed in a concentration of as low of 0.5 % by weight or as high as 20 % by weight and that not each and every polyol can be employed in a concentration of as low as 0.1 % or as high as 15 % by weight but that suitable concentrations of specific compounds within the broad ranges indicated in STROUD depend, *inter alia*, on the specific

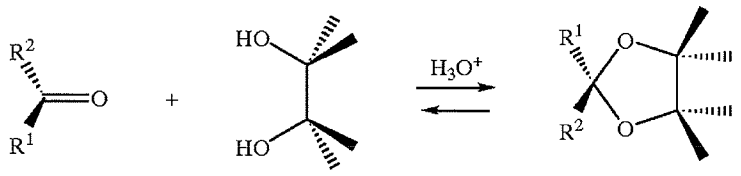
compounds employed and the type and the concentration of the additional compounds which are present in the compositions of STROUD.

Further, STROUD provides guidance with regard to suitable concentrations within the broad concentration ranges indicated therein for compositions in which dihydroxyacetone is the self-tanning skin coloring agent subject to chemical instability and a sugar alcohol such as (D-)sorbitol or mannitol is employed as the polyol.

In particular, all of the exemplified compositions of STROUD contain dihydroxyacetone in a concentration of from 4 % to 6 % by weight, in line with the statement in col. 10, lines 4-8 of STROUD that a preferred composition thereof contains dihydroxyacetone as the self-tanning skin coloring agent subject to chemical instability and contains this self-tanning skin coloring agent in a concentration of from 4.0 % to 6.0 % by weight.

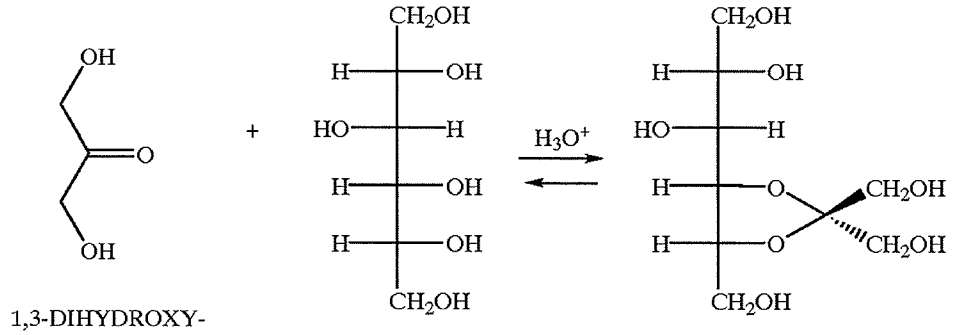
Further, all of the exemplified compositions of STROUD contain sorbitol as the polyol for stabilizing dihydroxyacetone in a concentration of from 0.7 % to 3.5 % by weight (assuming that all of the "sorbitol solutions" contain 70 % by weight of sorbitol as indicated in Table 3 of STROUD), with a weight ratio of dihydroxyacetone to sorbitol ranging from 1.4 : 1 (see Table 3 of STROUD) to as high as about 8:1 (see Table 2 of STROUD), corresponding to a molar ratio of dihydroxyacetone to sorbitol of from about 2.8 : 1 to about 16 : 1 (the molecular weight of dihydroxyacetone is about half the molecular weight of sorbitol).

Further, in column 27 and 28 of STROUD the stabilizing action of a polyol on, e.g., dihydroxyacetone is explained in terms of an (acid catalyzed) reversible formation of a cyclic ketal:



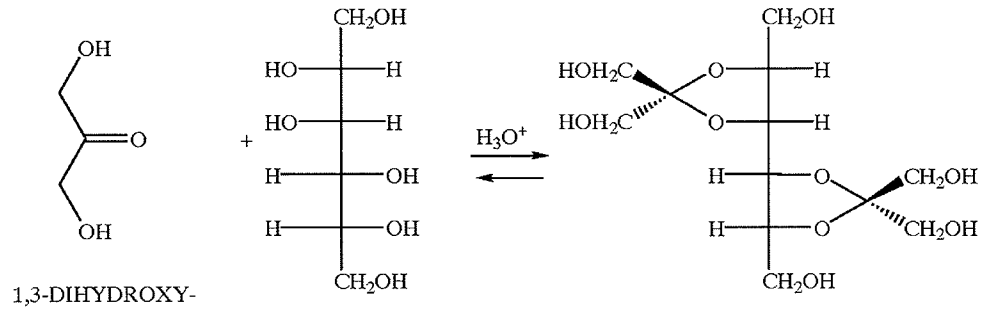
KETONE 1,2-DIOL CYCLIC KETAL

In particular, in the case of dihydroxyacetone and D-sorbitol the ketal formation may be represented by the following reaction scheme:



1,3-DIHYDROXY-ACETONE D-SORBITOL CYCLIC KETAL

As can be recognized from the above reaction scheme, despite the presence of additional hydroxy groups one molecule of D-sorbitol can form only <u>one</u> cyclic ketal ring with one molecule of dihydroxyacetone because the remaining hydroxy groups of D-sorbitol do not have the stereochemistry (cis configuration) that favors (or may even be necessary for) the formation of a 5-membered ketal ring. The situation is different in the case of mannitol where the stereochemistry of the hydroxyl groups allows the formation of up to two cyclic ketal rings per molecule of mannitol, as illustrated in the following reaction scheme:



(In this regard, it is apparent from col. 28, lines 45-47 of STROUD that in the reaction scheme at the bottom of the corresponding page "D-SORBITOL" should correctly read "MANNITOL").

Taking into account the exemplified compositions of STROUD and the explanations with respect to the mechanism of the stabilizing action of the polyol (i.e., by reversibly forming a cyclic ketal structure with dihydroxyacetone) set forth above, it is apparent to one of ordinary skill in the art that for a complete ketalization of dihydroxyacetone the molar ratio of dihydroxyacetone to sorbitol must not exceed 1:1 (i.e., an at least stoichometric amount of sorbitol is needed).

Further, the fact that despite a required molar ratio of sorbitol to dihydroxyacetone of at least 1 : 1 for a complete ketalization of dihydroxyacetone the molar ratio of sorbitol to dihydroxyacetone in the exemplified compositions of STROUD is not higher than about 1 : 2.8 (and as low as about 1 : 16) is a clear indication for one of ordinary skill in the art that the polyol is to be employed in (significantly) substoichiometric amounts.

In view of the foregoing, even if one were to assume, *arguendo*, that STROUD provides motivation to replace sorbitol by glycerol as the polyol in the dihydroxyacetone

containing compositions thereof, it is apparent to one of ordinary skill in the art that glycerol should be used in substoichiometric amounts with respect to dihdroxyacetone, i.e. the molar ratio of dihydroxyacetone to glycerol should be (significantly) higher than 1:1 (like sorbitol, glycerol can only stabilize one molecule of dihydroxyacetone at a time). Since dihydroxyacetone and glycerol have almost identical molecular weights this means that STROUD (implicitly) conveys the impression, if not teaches, that the weight ratio of dihydroxyacetone to glycerol should always be (significantly) higher than 1:1, contrary to what is recited in instant claims 37, 38, 40, 49 and 52.

Further, in view of the apparent teaching in STROUD that if dihydroxyacetone is used as the self-tanning skin coloring agent subject to chemical instability the concentration thereof should be in the range of from about 4 % to 6 % by weight (see, e.g., col. 10, lines 4-8 and the exemplified compositions of STROUD) and further in view of the fact that the lowest molar ratio of dihydroxyacetone to polyol (sorbitol) in the exemplified compositions of STROUD is about 2.8 : 1 (see above), the concentration of glycerol in a corresponding (theoretical) composition would not be significantly higher than about 2 to 3 % by weight (for an acetone concentration of 6 % by weight and a molar (weight) ratio of dihydroxyacetone to glycerol of 2.8 : 1 the corresponding acetone concentration would be about 2.2 % by weight), i.e., far less than the 5 % by weight of glycerin recited in instant claim 34, or the more than 8 % by weight of glycerin recited in, e.g., instant claim 35.

Appellants submit that in view of at least all of the facts set forth above, the allegations at pages 7 to 11 of the Examiner's Answer are clearly without merit. In this regard, it additionally has to be taken into account that even the 14 preferred self-tanning

skin coloring agents subject to chemical instability and the 18 preferred polyols or groups of polyols set forth in STROUD give rise to a total of 252 possible combinations of self-tanning agent and polyol (assuming no mixtures of polyols are employed). STROUD neither provides any motivation to pick a combination of dihydroxyacetone and glycerol from these 252 possible combinations, nor renders it obvious to employ glycerol in the concentrations and weight ratios with respect to dihydroxyacetone recited in the instant claims (see explanations above).

To sum up, for the reasons set forth above and the additional reasons set forth in the Appeal Brief, the Examiner has failed to establish a *prima facie* case of obviousness of the subject matter of any of the instant claims, wherefore reversal of the rejections under 35 U.S.C. § 103 of record is warranted.

CONCLUSION

The request to reverse the rejection of claims 34-56 and to return the application to the Examining Group for prompt allowance is respectfully maintained.

Although no fee is believed to be required for entry of this Reply Brief, the Patent and Trademark Office is hereby authorized to charge any fee that is deemed to be necessary to Deposit Account No. 19-0089.

Respectfully submitted,
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April 14, 2011
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